A cost-to-benefit analysis of blood products used during the initiation of an orthotopic liver transplantation programme

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Orthotopic liver transplantation (intervention) versus standard medical and non-transplant surgical management of variceal bleeding (major complication of liver disease) with sclerotherapy, blood transfusions, hospitalisation and, when unavoidable, a single operation in patients with end-stage post-necrotic and cholestatic liver diseases.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with end-stage post-necrotic and cholestatic liver diseases.

Setting
Hospital. The economic study was carried out in Cape Town, South Africa.

Dates to which data relate
The data for resources used and effectiveness, for the intervention, were recorded between October 1990 and May 1991. No specific date was reported for the prices used. The benefit results were extracted from studies published between 1984 and 1989.

Source of effectiveness data
Effectiveness data were derived from a single study, and a literature review.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations did not determine the sample size. Ten patients were studied in the intervention group.

Study design
Prospective case series carried out in a single centre. The median duration of follow up was more than 4 years.
Analysis of effectiveness
The principle (intention to treat or treatment completers only) was not specified. The primary health outcomes used were mortality, full blood count, haemostatic evaluation, fibrinogen and fibrinogen degradation products (FDPs), antithrombin III (using Chromatic: General Diagnostics, NJ, USA) and protein C levels.

Effectiveness results
The occurrence of 1 death at 2 weeks of intervention was linked to fungaemia and gastrointestinal bleeding. Haemoglobin levels and platelet counts remained stable throughout all phases of the surgical procedure. The international normalised ratio (INR) and activated partial thromboplastin time (APTT) were prolonged during transplantation, but had returned to normal within 24 hours. Fibrinogen levels all had returned to normal within 24 hours of surgery. Despite the variability in FDPs in one of the phases of the intervention, the values returned to below 80 micro g/ml within 24 hours of reperfusion. Factor V and protein C, despite important previous decreases, showed a prompt return to normal (within 24 hours) following reperfusion. Factors VII, IX, X and XII, plasminogen and alpha-2 antiplasmin and antithrombin III plasma levels remained within acceptable limits.

Clinical conclusions
The subgroup of individuals transplanted because of post-necrotic cirrhosis started off with more severely deranged tests of haemostasis and required more blood products and this diagnosis should therefore be regarded as predictive of large-volume transfusion requirements.

Outcomes assessed in the review
The likelihood that the patients will be alive between 5 and 10 years and the quality of life.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Six published studies were included in the review.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.
Results of the review
It was reported that, in the intervention group, "there is a 90% likelihood that the recipients will be alive between 5 and 10 years, able to work, self-supporting and capable of enjoying an excellent quality of life" (although a figure of 80% was given in the summary). For the comparator, "most will probably be dead within 3 years and during this time unable to work. They will have a poor quality of life".

Measure of benefits used in the economic analysis
The main benefit measures were the likelihood that the patients will be alive between 5 and 10 years and the quality of life. The benefits were extracted from the literature and reported descriptively.

Direct costs
No discounting was reported and quantities were not analysed separately. Cost items were broadly reported separately. Costs measured were operational costs (hospital costs and surgery, including blood products administered). The boundary adopted was not explicitly specified. The estimation of quantities was based on actual data (medians). The unit costs were calculated from the institution's costs. The dates of the price data were not reported.

Indirect Costs
Not considered.

Currency
South African rand (R).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
It was reported that, in the intervention group, "there is a 90% likelihood that the recipients will be alive between 5 and 10 years, able to work, self-supporting and capable of enjoying an excellent quality of life" (although a figure of 80% was given in the summary). For the comparator, "most will probably be dead within 3 years and during this time unable to work. They will have a poor quality of life".

Cost results
Median costs for the intervention at 1 year and 5 years were R35,000 and R60,000. For the comparator, the corresponding estimated figures were R30,000 and R70,000 at 1 and 3 years.

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors' conclusions
The results support the continued application of intervention in selected patients. It is demonstrably superior to conventional treatment, being less expensive and resulting in more favourable outcome when measured by both survival and quality of life.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.
Validity of estimate of measure of benefit
The estimates of benefit results may not be internally valid due to lack of randomisation, absence of a comprehensive literature review, and no clear quality assessment of the primary studies included in the review. The internal validity may be further weakened by the descriptive nature of the benefit results, and the discrepancy between the value of survival probability reported in the summary and the main body of the paper (80% in the summary versus 90% in the main body of the paper).

Validity of estimate of costs
Quantities were not reported separately from the costs and dates for the prices used were not reported. The authors did not report on which group of patients the costing for the comparator was carried out or when it was performed. The costs were not discounted although this would appear to have been methodologically necessary.

Other issues
Given the concerns mentioned above the results should be treated with some caution.

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